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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,886	11/06/2003	Michiel Onne Elema	05432/100K425-US1	9219

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EXAMINER	
HOWARD, SHARON LEE	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,886	ELEMA ET AL.	
	Examiner	Art Unit	
	Sharon L. Howard	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The examiner acknowledges receipt of the IDS filed on 11/6/03.

Election

This application contains claims directed to the following patentably distinct species of the claimed invention: The therapeutically active medicament is:

1. Citalopram (Claim 14)
2. Escitalopram (Claim 15)
3. Gaboxadol (Claim 16)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Jay Lessler on September 17, 2004 a provisional election was made with traverse to prosecute the species of Citalopram, claim 15. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14 and 16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13,15,17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koch et al. (USP 5,912,256).

Koch teaches pharmaceutical compositions known in the art for treating diseases which are caused by disorders of the serotonin-affected neurological systems (see col.1, lines 8-14). Koch discloses compositions such as tablets, chewable tablets and capsules are known to be used. Koch teaches that tablets are prepared by wet or dry granulation and usually contain diluents and binders such as, for example lactose, starch, sugar, sodium chloride, natural and synthetic gums such as acacia, alginates. Koch also teaches that disintegrators, polyethylene glycol which defines a binder and a polymer consisting of ethylcellulose (see col.23, lines 51-67 and col.24, lines 8-32) are formulated into the tablets. Koch teaches Citalopram (see col.21, lines 15 and 16). Absent a showing in the criticality of the particular drug, there are no unexpected results since the prior art teaches Citalopram which is a homologue of Escitalopram.

Koch does not teach the amount of the hydrophilic cellulose ether polymer nor the amount of the hydrophilic melt binder.

However, one of ordinary skill in the art would be able to determine the particular amounts through routine experimentation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the Koch reference because Koch teaches a wet granulated composition comprising a polymer, a binder and a drug. The expected result would be a pharmaceutical composition which is compressed into tablets.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to

identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 1 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 5,403,593. This is a double patenting rejection. Claim 1 of '593 recites a composition for preparing a therapeutically active sustained release dosage form which comprises a melt granulated substantially homogeneous mixture comprising A) a hydrophilic cellulose ether polymer, B) a granulating medium comprising polyethylene glycol and C) a therapeutically active medicament is the same as that of claim 1 of the instant application.

Claims 2 and 3 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 2-4 of prior U.S. Patent No. 5,403,593. Claims 2-4 of '593 recite that the average molecular weight of polyethylene glycol is about 3,000 to 9,000. This is a double patenting rejection.

Claims 4-6 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 5-7,9-14 of prior U.S. Patent No. 5,403,593. Claims 5-7,11 of '593 recite that hydrophilic cellulose ether polymer comprises hydroxypropylmethylcellulose. This is a double patenting rejection.

Claims 10-12 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 15 and 16 of prior U.S. Patent No. 5,403,593. Claims 15 and 16 of '593 recite the same composition comprising A) 30 to 40% of hydrophilic cellulose ether

polymer B) 15 to 30% of a granulating medium comprising 5 to 20% of polyethylene glycol C) a therapeutically active medicament. This is a double patenting rejection.

Claim 13 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 17 prior U.S. Patent No. 5,403,593. Claim 17 encompasses claim 13 of the instant application. Claim 17 recites that PEG consists of PEG 3350, PEG 4600, PEG 8000. This is a double patenting rejection.

Claim 19 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 23 prior U.S. Patent No. 5,403,593. Claim 23 recites that the composition is in tablet form. This is a double patenting rejection.

Claim 20 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 21 of prior U.S. Patent No. 5,403,593. Claim 21 recites the same process for preparing a therapeutically active composition comprising a) forming a molten mass by applying heat to a composition comprising A) a hydrophilic cellulose ether polymer B) a granulating medium comprising PEG, which is a hydrophilic melt binder and C) a therapeutically active medicament, b) mixing the mass to provide a substantially homogenous composition and c) cooling the mixture to room temperature. This is a double patenting rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (571) 272-0596. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharon Howard

Sharon Howard
September 17, 2004

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600